

Applicant : Nikolaos Soukos et al.  
Serial No. : 10/019,837  
Filed : September 10, 2002  
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Attorney's Docket No.: 00786-421002 / MGH 1429.1

Amendments to the Drawings:

The attached replacement sheet of drawings includes changes to Fig. 1 and replaces the original sheet including Fig. 1 and Fig. 2

In Amended Figure 1, the laser pulse 20 was indicated, and stress wave 22 was properly identified.

Attachments following last page of this Amendment:

Replacement Sheet (1 page)  
Annotated Sheet Showing Change(s) (1 page)

### REMARKS

#### **Rejections under 35 U.S.C. §112**

1. The Examiner rejects claims 1-18 and 22-27 as not complying with the enablement requirement of 35 U.S.C. §112, first paragraph. In particular, the Examiner cites page 8, line 21 of the specification (“The target material must be coupled to the biofilm by a coupling medium”) as limiting the invention to those embodiments in which a coupling medium is used.

This sentence must be read in context. The context for the cited sentence is set at the beginning of the page: “*When the stress wave is generated by irradiation of a target material....*”<sup>1</sup> That context is carried to the next paragraph: “Many types of materials can be used as the target material *in conjunction with a laser beam....*”<sup>2</sup> In this context, it is clear that the target material “must” be coupled to the biofilm *only* when the stress wave is generated by irradiation of a target material. Since none of the rejected claims are directed to a method, using a target material in the absence of coupling medium, Applicant respectfully requests reconsideration of this rejection.

2. The Examiner rejects claims 1-4, 13-23 and 25-27 as not complying with the enablement requirement of 35 U.S.C. §112, first paragraph. In particular, the Examiner cites page 8 of the specification as requiring the use of a target material. On the contrary, page 7 discloses a variety of alternative means for generating stress waves, including lithotripters, transducers, explosive reactions in energetic materials, and fiber optics. Any of these alternative methods can be used, e.g., to “propagate a sufficient number of stress waves into the biofilm...” as recited in claim 1. Applicant respectfully requests reconsideration of this rejection.

3. The Examiner has rejected claims 1-27 as not complying with the written description requirement of 35 U.S.C. §112, first paragraph. Applicant has amended the specification and the

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<sup>1</sup> Specification, page 8, line 2 (emphasis added).

<sup>2</sup> Specification, page 8, line 7 (emphasis added).

diagrams to enhance their clarity. With regard to The Examiner's objection to the term "capsular," Applicant submits that the meaning of that term is known to one of ordinary skill in the art and needs no explicit definition within the specification.

4. The Examiner has rejected claims 1-27 under 35 U.S.C. §112, second paragraph. Applicant has amended claims 1, 8, 9, 12, 24, and 26 to more particularly point out and distinctly claim the subject matter which the applicant regards as the invention. However, Applicant does not believe further clarification is warranted with regard to claims 15, 19 and 22.

In claim 15, the Examiner maintains that "capsular polysaccharide" has not been defined in either the claim or the specification, and is therefore vague and indefinite. The specification makes clear that "a biofilm may contain microbial cells [and] extracellular substances, such as proteins or polysaccharides, e.g. capsular polysaccharides expressed by the microbe." Furthermore, Applicant maintains that the phrase "capsular polysaccharide" has a known meaning within the art. Applicant therefore respectfully requests reconsideration of this objection.

In claim 19, The Examiner maintains that the term "suitable" in the phrase "a coupling medium suitable for mixing with the compound..." is ambiguous. The Examiner considers the phrase unclear as to whether "the coupling medium actually mixes with the compound or not, or if the coupling medium is merely suitable for mixing with the compound."<sup>3</sup>

Applicant means to claim the latter. Applicant maintains that "suitable for mixing with" has a meaning distinct from "mixed with."<sup>4</sup>

Additionally, The Examiner maintains that "it is not clear how the target material, reservoir, and coupling medium relate to each other, spacially [sic] and process-wise."<sup>5</sup> Figure 1 illustrates one of many possible embodiments having the limitations recited in claim 19. Despite diligent effort, Applicant is unable to identify a lack of clarity in the claim language. Applicant respectfully requests that the Examiner further articulate the alleged lack of clarity. In the alternative, Applicant respectfully requests reconsideration of this rejection.

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<sup>3</sup> Office Action, page 5.

<sup>4</sup> For example, any ordinary dairy cow can produce cream which is "suitable for mixing with" coffee. It would take quite an unusual dairy cow to produce cream which *is mixed* with coffee.

<sup>5</sup> Office Action, page 4.

In claim 22, the Examiner also maintains that the meaning of “associated” is unclear. Applicant submits that the meaning of “associated” can be found in the discussion beginning on page 5, line 8 and ending on page 6, line 11, in which biofilms are described as being found “in association with” a number of various other conditions. The Examiner appears to interpret “associated” in claim 22 as calling for a structural relationship (“Does it mean that the biofilm is attached to the surface, near the surface, a part of the surface?”<sup>6</sup>) To the contrary, the phrase “associated” should be understood in the context of pages 5-6 of the specification. For example, a biofilm is associated with a surface if the biofilm is a byproduct of organisms living on the surface. This is, of course, not the only condition in which a biofilm may be “associated” with a surface. Applicant respectfully requests reconsideration of this rejection.

#### **Section 103 rejection based on *Flotte***

Applicant amends claims 1, 24, and 26 to recite a method of delivering a compound or therapeutic agent *to the matrix* of a biofilm.

*Flotte* describes a method based on “[t]he interaction of pressure waves with biological tissues, cells, and macromolecules...”<sup>7</sup> As best understood, the Examiner has rejected claims 1-27 on the understanding that a biofilm includes cells, and since *Flotte* describes a method of delivering a compound to a cell, *Flotte* also describes a method of delivering a compound to a biofilm.

Conspicuously absent from *Flotte* is any method applicable to delivering a compound to the matrix of a biofilm. *Flotte* teaches that stress waves cause aqueous pore formation, for example in cell walls.<sup>8</sup> It is these pores that account for the increased permeability in cells, tissues, and macromolecules. In contrast, the matrix of a biofilm does not have a cell wall, or indeed any structure amenable to aqueous pore formation. Thus, one of ordinary skill in the art would conclude from *Flotte* that stress waves would be ineffective at permeabilizing the matrix of biofilm. For at least this reason, Applicant respectfully requests reconsideration of this rejection.

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<sup>6</sup> Office Action, page 4.

<sup>7</sup> *Flotte*, page 160.

<sup>8</sup> *Flotte*, page 162.

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All of the dependent claims are patentable for at least the reasons for which the claims on which they depend are patentable.

Any circumstance in which the applicant has (a) addressed certain comments of the The Examiner does not mean that the applicant concedes other comments of the The Examiner, (b) made arguments for the patentability of some claims does not mean that there are not other good reasons for patentability of those claims and other claims, or (c) amended or canceled a claim does not mean that the applicant concedes any of the The Examiner's positions with respect to that claim or other claims.

No fee is believed to be due. If a fee is due or a refund is forthcoming, please apply any other charges or credits to deposit account 06-1050, referencing 00786-421002.

Respectfully submitted,

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